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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,790	11/21/2003	David William Banner	21500	5703

151 7590 03/02/2006

HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

EXAMINER

FREISTEIN, ANDREW B

ART UNIT PAPER NUMBER

1626

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/720,790	Applicant(s) BANNER ET AL.	
	Examiner Andrew B. Freistein	Art Unit 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 62-64, 66 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-61 & 65 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/18/05; 11/21/03</u> | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

Claims 1-67 are currently pending in the instant application.

***Priority***

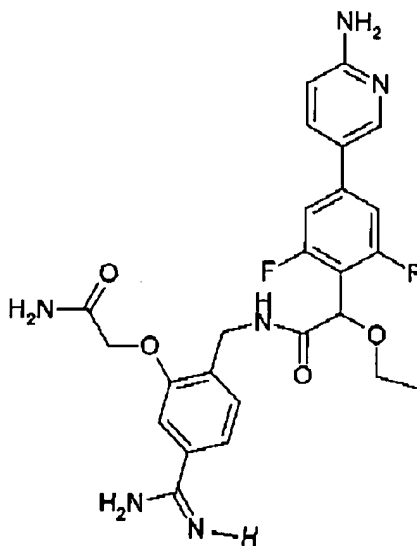
Acknowledgement is made of Applicant's claim for foreign priority under 35 U.S.C. § 119(a)-(d), by European patent application 02026365.3 filed on 11/25/2005.

***Information Disclosure Statement***

Applicant's information disclosure statements (IDS), filed on November 21, 2003 and November 18, 2005, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

***Response to Restriction Requirement***

Acknowledgement is made of Applicant's election (with traverse) of Group I, claims 1-61 and 65, and the species (RS)-2-[4-(6-Amino-pyridin-3-yl)-2,6-difluorophenyl]-N-(4-carbamimidoyl-2-carbamoylmethoxy-benzyl)-2-ethoxy-acetamide, which



has the chemical structure

in a response filed January

26, 2006.

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Applicant traverses the restriction requirement asserting that the claims are directed to the same inventive concept and no undue search burden exists.

The Examiner respectfully disagrees with the Applicant because the products of Inventions I-IV differ materially in structure and element and from each other and are therefore capable of supporting their own patents. The invention groups I-IV are related to a set of structurally diverse compounds, their methods of use, and methods of preparing diverse compounds. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The chemical structures claimed do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Due to the plethora of classes and subclasses in each of group, separate search considerations are involved, which would impose a serious burden on the Examiner.

Nevertheless, Examiner may reconsider to rejoin the method of use claims and the methods of preparation claims commensurate in scope with the product claims when and if the case is found to be in condition for allowance provided those method of use claims and method of preparation claims are free of 35 U.S.C. § 112 first and second paragraph issues (including written description, reach-through claim language and/or scope of enablement issues).

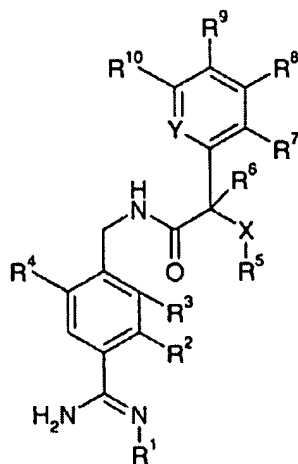
Applicants reserve their right to file a divisional application on the non-elected subject matter.

### ***Status of the Claims***

Claims 1-61 and 65 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

### **Elected and Examined Subject Matter**

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



Compounds of the Formula (I),

, wherein:

**R<sup>1</sup>** is as defined in claim 1;

**R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup>** are as defined in claim 1, but do not include heterocyclic groups;

**R<sup>5</sup>** is as defined in claim 1;

**R<sup>6</sup>** is as defined in claim 1;

**Y** is C-R<sup>11</sup>;

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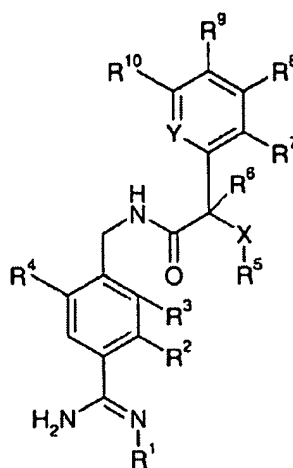
$R^7$ ,  $R^8$ ,  $R^{10}$  and  $R^{11}$  are as defined in claim 1, but do not include heterocyclic groups, and are not bound together;

$R^9$  is an optionally substituted saturated or unsaturated heterocyclic group; and

$X$  is O, S, or  $SO_2$ .

### Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:



Compounds of the Formula (I),

, wherein:

$R^2$ ,  $R^3$  and  $R^4$  include heterocyclic groups;

$Y$  is N;

$R^7$ ,  $R^8$ ,  $R^{10}$  and  $R^{11}$  include heterocyclic groups, or  $R^8$  and  $R^9$  or  $R^8$  and  $R^7$  are bound to each other to form a ring together with the carbon atoms to which they are attached;

$R^9$  is as other than an optionally substituted saturated or unsaturated heterocyclic group, or is bound together with  $R^8$  to form a ring together with the carbon atoms to which they are attached;

$X$  is  $NR^{12}$ ; and

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**R<sup>12</sup>** is as defined in claim 1.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 1-61 and 65 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as, piperazine, morpholine, oxazol, pyrimidine, pyrazine, pyran, furan, indole, benzoxazole, etc. which are chemically recognized to differ in structure, function, and reactivity.

Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

### ***Claim Objections***

Claims 1-61 & 65 are objected to as being drawn to non-elected subject matter.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein  
Patent Examiner, AU 1626

KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read "Kamal Saeed", written in dark ink over a horizontal line.

Kamal Saeed, Ph.D.  
Primary Patent Examiner, AU 1626  
Date: February 23, 2006